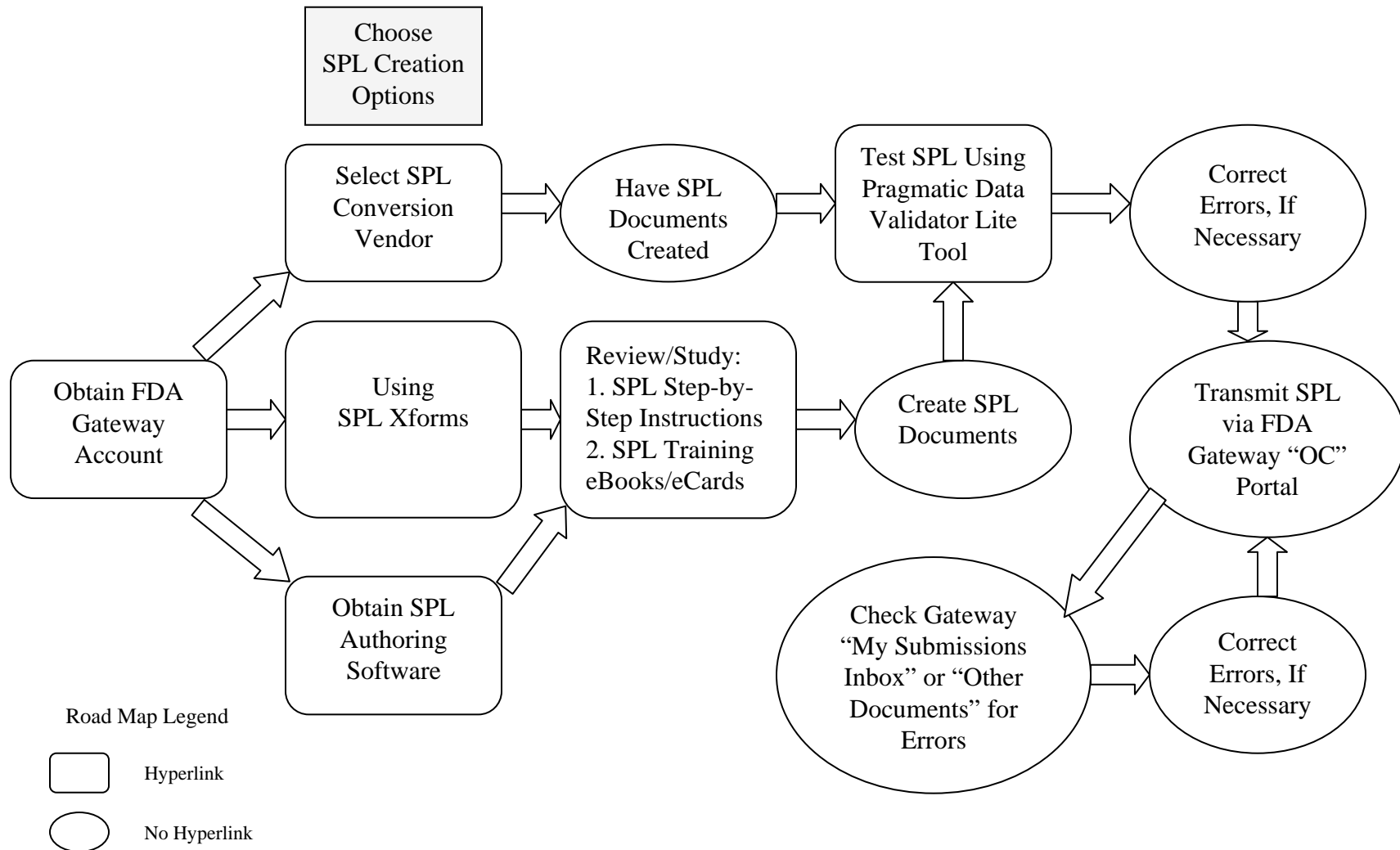


SPL - Preparing Repacked/Relabeled Drug Product Electronic Drug Listing Submissions

Lonnie Smith
Policy Analyst
FDA Data Standards Council

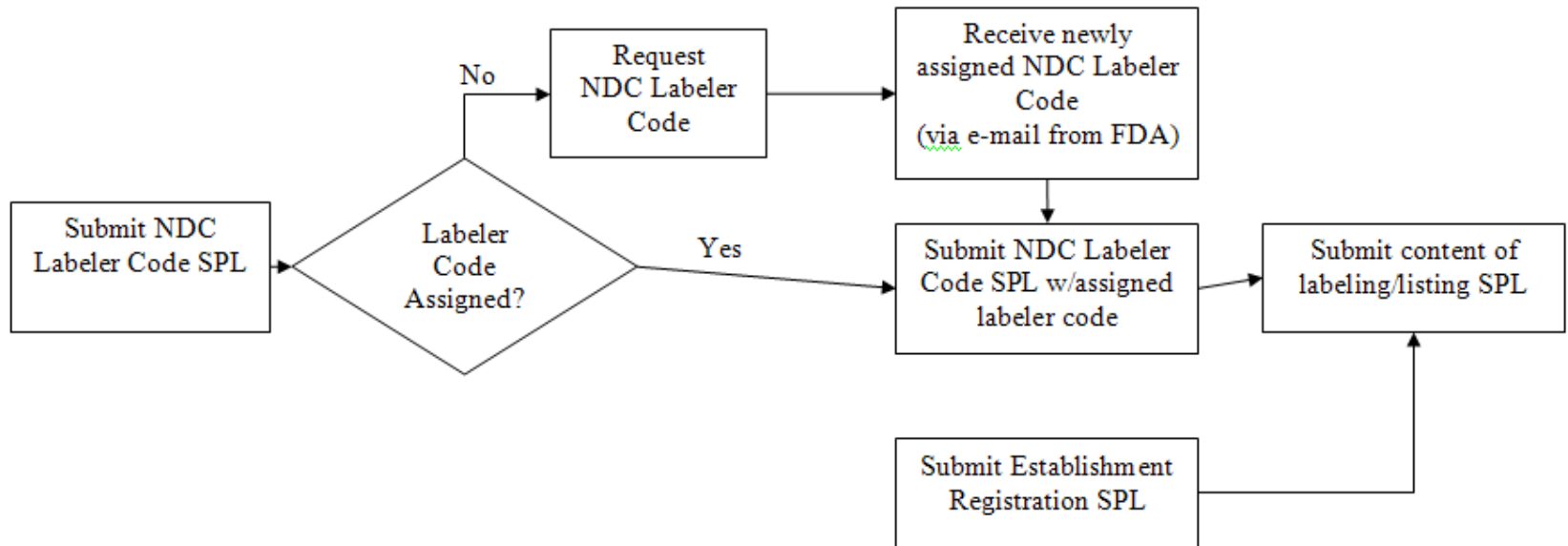


“Road Map” Creation & Submission



SPL Submission Process

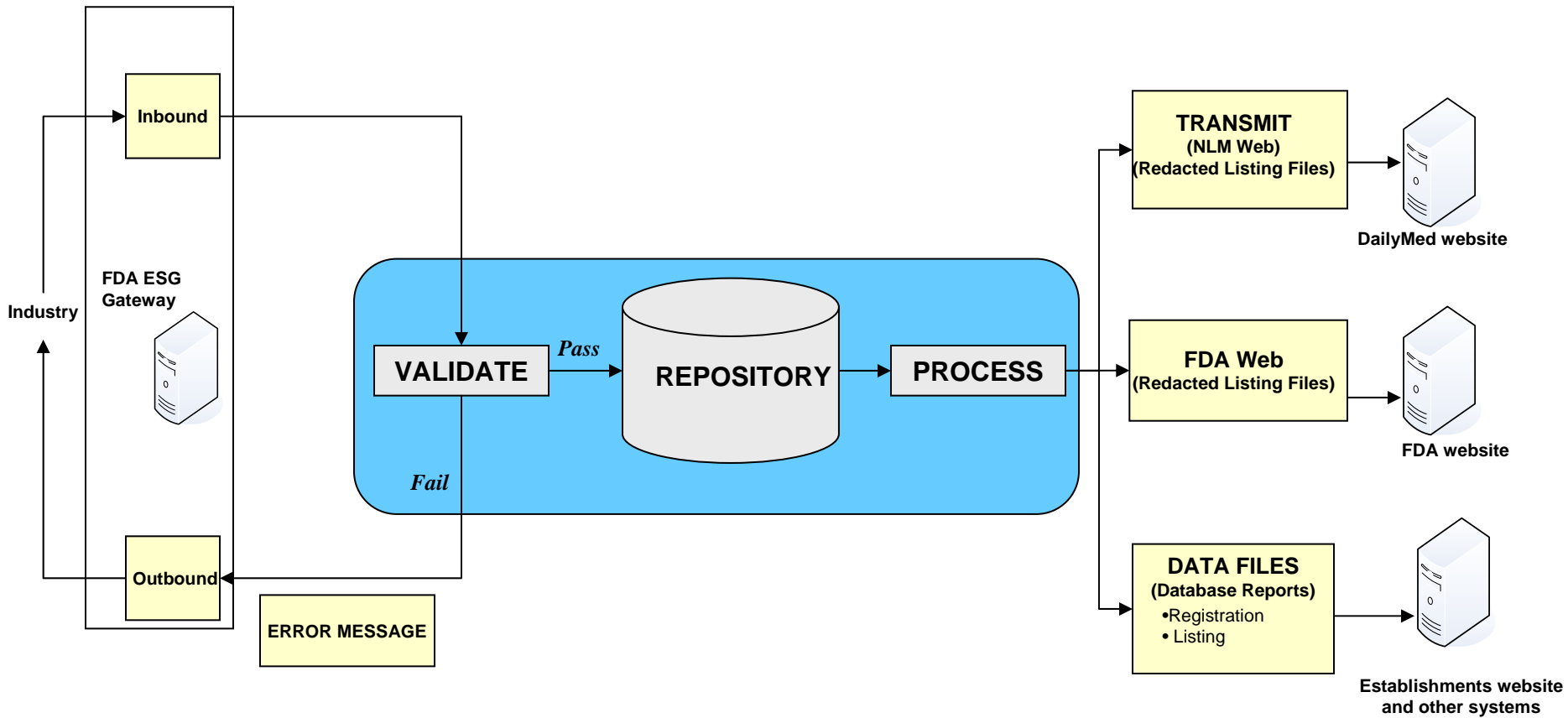
Drug Listing ONLY



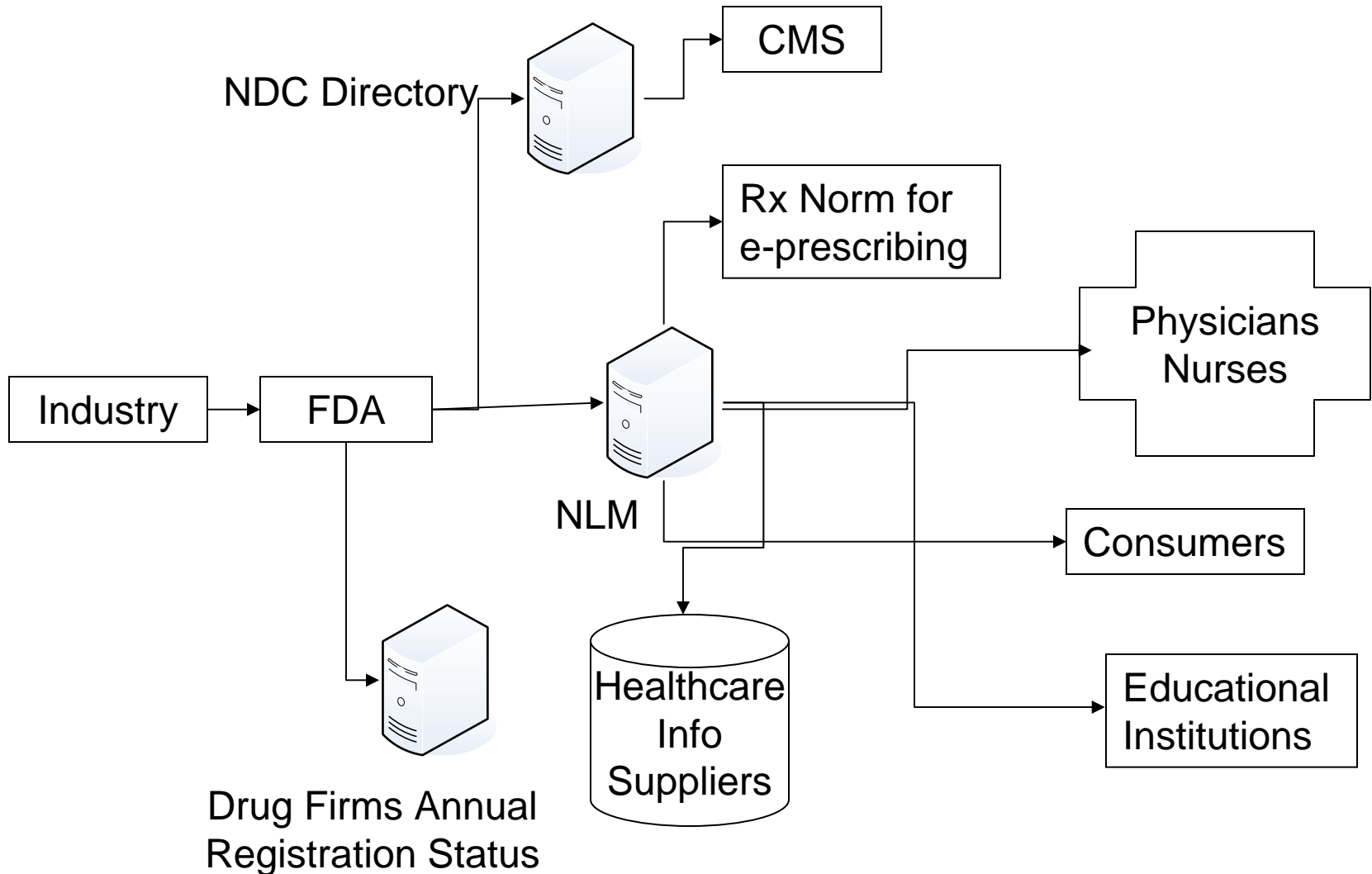
Technical Terms Glossary

Term	Definition
Core ID	•A unique identifier which the FDA ESG assigns to every submission and uses for reference purposes
Document Root ID	•Globally Unique Identifier (GUID) and is unique for each version of the document. Also referred as “root ID,” “ID,” “document ID,” or “document root ID.”
Effective Time	•Provides a date reference to the SPL document version or a section including the year, month and day as yyyyymmdd.
GUID	•Globally Unique Identifier (used as the SPL document root ID, setID, or section IDs)
SetID	•Globally Unique Identifier (GUID) and is a unique identifier for the document that remains constant through all versions/revisions of the document.
UUID	•Universal Unique Identifier (UUID) Synonymous w/GUID (see definition for GUID)
Version Number	•Integer greater than zero that provides a sequence to the versions of the document.

eLIST



Data Sharing



Content of Labeling

- Methods for providing the manufacturer's content of labeling
 - Create the content of labeling via data entry
 - Download current version of manufacturer's label from DailyMed (change document IDs and setIDs)

Medication Guides

- **ASAP!** - Please check all previously submitted SPL files to ensure that medication guide section are properly coded using the medication guide section header and code.

Doc IDs & SetIDs in Repacked Drug SPL Documents

- Change the doc IDs, section IDs, & setIDs of the manufacturer's SPL if you reuse their label (SPL).
- Once you submit your first valid version of the SPL with your setID, the setID must remain constant throughout lifecycle of SPL.
- Change the images of the carton/container labels to images of your carton/container labels

DailyMed's RSS Feed

- DailyMed's Really Simple Syndication – automatic notification when your newly posted files or the manufacturer's newly posted files are available on DailyMed.
- Use to determine when original manufacturers' SPL files are updated.

DailyMed's RSS Feed Info

- **DailyMed RSS Feed : Update Notices to Your Reader**
- <http://dailymed.nlm.nih.gov/dailymed/rsshome.cfm>
- **What is RSS?**
- RSS (Really Simple Syndication) is a format for sharing and distributing Web content. Using an RSS reader, you can get updates and information about new drug labels approved by the FDA and published on NLM's DailyMed Web site. RSS Readers (also called Aggregators) will download the DailyMed RSS feed for you.
- **How do I get a RSS Reader?**
- There are many free RSS Readers available for download via the Internet and more are added each day. They give you a variety of functions and each has its own advantages.
- NLM or DailyMed does not endorse any particular reader or aggregator. To find one that fits your needs simply search the Internet entering the key words *Free RSS Reader*. Or, you may select one of the RSS Reader applications here:

[List of RSS Readers - in the Internet Open Directory.](#)

Labeler Information in Listing SPL

- The labeler uses their assigned NDC Labeler Code to create the NDC for the drug product. The information includes the name and DUNS Number.

Labeler - Labeler name here (labeler DUNS Number here)

Establishment Information in Listing SPL

- Name
- DUNS number
- Mark as Confidential (check box)
- Type(s) of operations (include “repack or relabel for your drug establishment

Establishment			
Name	Address	ID/FEI	Operations
Establishment name here		Establishment DUNS Number here	manufacture

Establishment			
Name	Address	ID/FEI	Operations
Establishment name 2 here		establishment DUNS Number here	manufacture

Establishments in Listing SPL

- The establishments are the entities involved in the manufacturing or processing the drug product.
- Enter one or more establishments.
- The information includes the name, DUNS Number and types of operations.
 - Types of operations for an establishment in the listing SPL should also be one of the types of operations for that establishment in Establishment Registration SPL.

Identifying Manufacturer of Repacked Product

- Include name, DUNS Number and type of operation of manufacturer
- The Source NDC Product Code is used when a marketed drug product is repacked or relabeled.
- Add source NDC Product Code of manufacturer's drug
- Only one source NDC Product Code per repacked drug product (table)

Source NDC Product Code

- Enter original manufacturers' NDC Product Code for the product in the source NDC Product Code field.
- NDC Product Code – first two segments of the three-segment NDC.

Product Data Elements

- Product
 - Product names
- Description
 - Ingredients
 - Strength
 - Dosage form
 - Route of administration
 - Controlled substance code
 - Appearance
- How supplied
 - Packaged product

Only terms in the controlled terminology are allowed.

Strength of Ingredient

- SPL R4 documents will allow companies to **designate strength based on the active ingredient, active moiety or a reference drug.**

Example of non-solid dosage form

Numerator: **10 mg**

Denominator: **1 mL**

Example of solid dosage form

Numerator: **10 mg**

Denominator: **None**

Strength cont...

Product	Numerator unit	Denominator unit
Oral solid	Weight	Each
Oral liquid	Weight	Volume
Oral powder for reconstitution with a known volume	Weight	Volume
Oral powder for reconstitution with a variable volume	Weight	Each
Suppository	Weight	Each
Injection liquid	Weight	Volume
Injection powder for reconstitution with a known volume	Weight	Volume
Injection powder for reconstitution with a variable volume	Weight	Each
Inhaler powder	Weight	Each
Inhaler liquid	Volume	Each
Inhaler blister	Weight	Each
Topical cream or ointment	Weight	Weight
Topical gel or lotion	Weight	Volume
Transdermal patch	Weight	Time
Bulk liquid	Weight	Volume
Bulk solid	Weight	Weight

Marketing Category

- Select the appropriate marketing category for the drug product.

Marketing Information	
Marketing Category	
NDA	

Application or Citation Number

- Application numbers include the character application abbreviation and the numbers without spaces or dashes (e.g., NDA123456). Monograph citations include the number of the regulatory part (e.g., part234).

	Application Number or Monograph Citation
	NDA000000

Marketing Status & Date

- The marketing status describes the activity of the product
- SPL file is removed from the public repository. The expiration date of the last lot released to the marketplace provides an estimate of the date when the SPL file is removed.

Marketing Status & Dates

- Status of product
 - **Active:** on the market
 - **Completed:** when marketing is done the drug is no longer going to be available on the market.
 - Active or completed timestamp: effectiveTime value.
- Low value
 - Time on the market
 - Determines release of CoL/Listing SPL to public
- High value
 - Time off the market (e.g. the expiration date of the last lot released to the market.)

Marketing Start Date	Marketing End Date
01/24/2005	

Submitting Files via FDA Gateway

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center: **Select the "OC" center**

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path: **Browse...** **Ensure that you are submitting SPL in a folder (file name should not appear in the path field)**

Root directory: **Browse...**

Submission type: **Select "SPL" as the submission type**

Select a signing certificate

Current file: M:\SPL_Main\gateway\Lonnie Smith\Lonnie Smith.p12

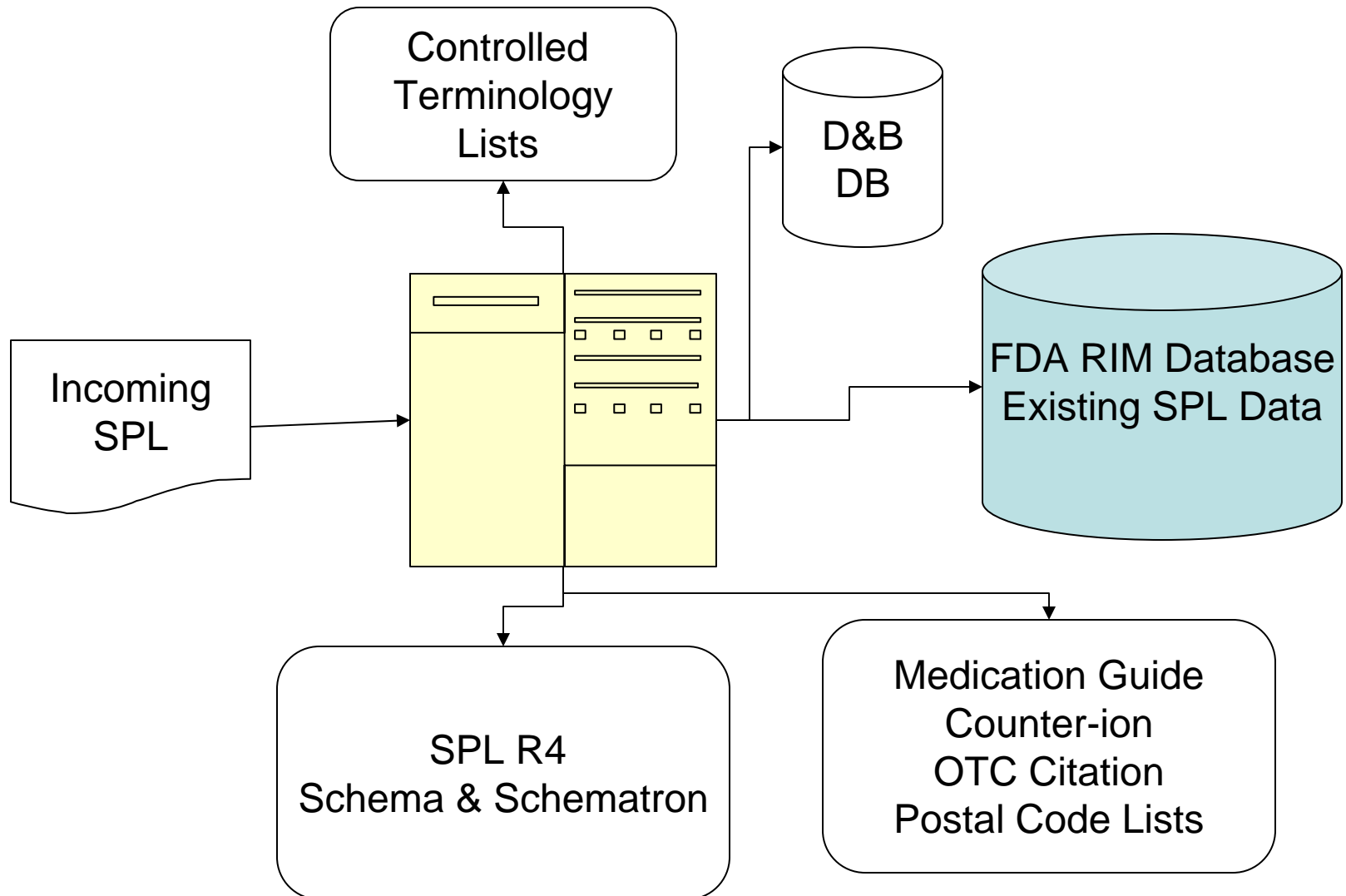
New file: **Browse...**
MyCertificate.p12 or MyPrivateKey.pfx

Send

Updating SPL Document Tracking Information

- **Use**
 - **new** id root
 - **new** version number
 - original setId
 - appropriate effective time
- **Misplaced SetID/SPL File**
 - E-mail core ID to spl@fda.hhs.gov
- Include contact person's name and DUNS Number which were included in original SPL file

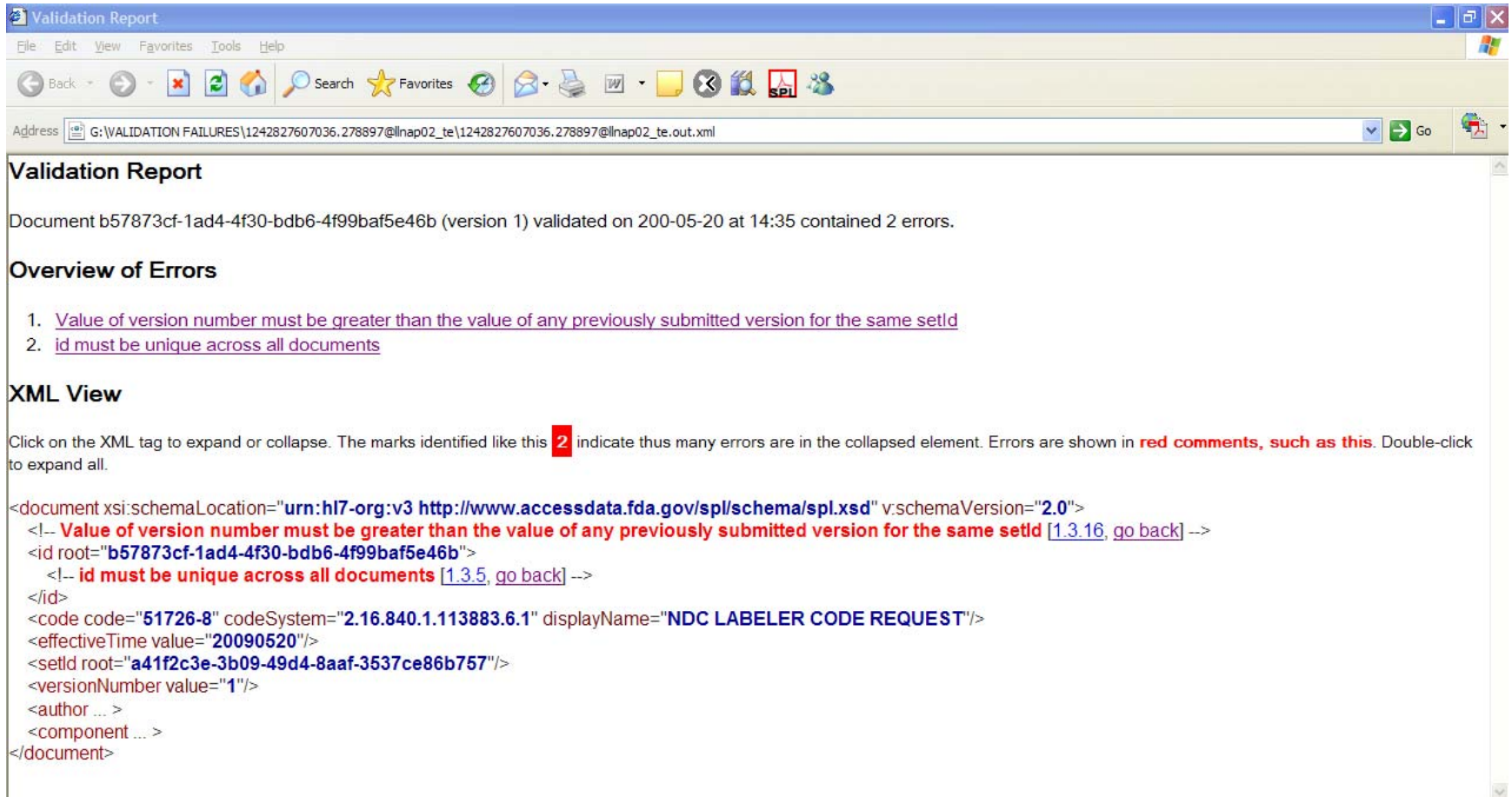
Validation Model



Validation Error Notifications

- Transmitted via FDA Gateway to submitter
- Transmissions occur within 36 hours (business days)
- In the form of a 2nd or 3rd acknowledgment
 - 2nd acknowledgment – system-generated message
 - 3rd acknowledgment – manually generated message with additional notes
- No 2nd or 3rd acknowledgment within 24 hours usually denotes that submission was accepted

Sample System Generated Validation Report



Validation Report

Document b57873cf-1ad4-4f30-bdb6-4f99baf5e46b (version 1) validated on 200-05-20 at 14:35 contained 2 errors.

Overview of Errors

- [Value of version number must be greater than the value of any previously submitted version for the same setId](#)
- [id must be unique across all documents](#)

XML View

Click on the XML tag to expand or collapse. The marks identified like this **2** indicate thus many errors are in the collapsed element. Errors are shown in **red comments, such as this**. Double-click to expand all.

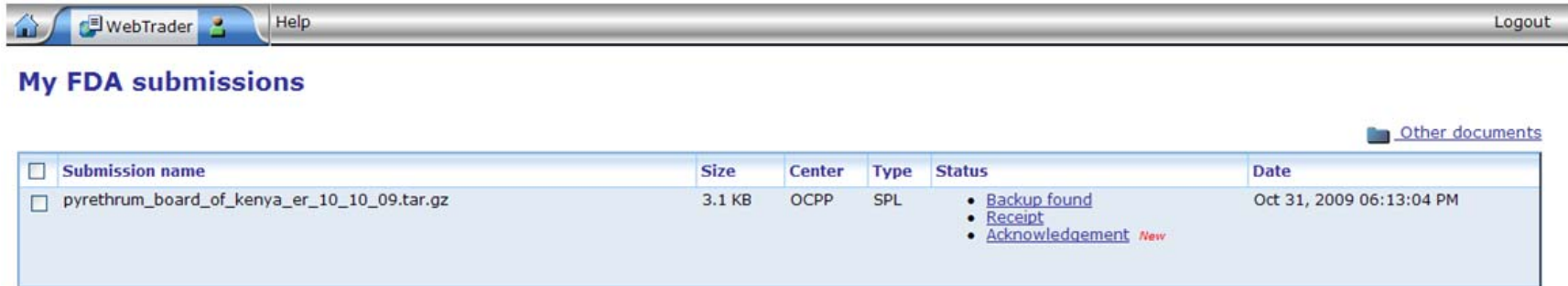
```
<document xsi:schemaLocation="urn:hl7-org:v3 http://www.accessdata.fda.gov/spl/schema/spl.xsd" v:schemaVersion="2.0">
  <!-- Value of version number must be greater than the value of any previously submitted version for the same setId [1.3.16, go back] -->
  <id root="b57873cf-1ad4-4f30-bdb6-4f99baf5e46b">
    <!-- id must be unique across all documents [1.3.5, go back] -->
    </id>
    <code code="51726-8" codeSystem="2.16.840.1.113883.6.1" displayName="NDC LABELER CODE REQUEST"/>
    <effectiveTime value="20090520"/>
    <setId root="a41f2c3e-3b09-49d4-8aaf-3537ce86b757"/>
    <versionNumber value="1"/>
    <author ... >
    <component ... >
  </document>
```

Test Your SPL R4 Docs

- Provision of SPL R4 Validator Tool
- Test SPL R4 files prior to submission
- Discover ~90 – 95% of validation errors prior to submission.
- Schematron technology – permits quick updates to validation procedures
- FDA in collaboration with Pragmatic Data made available a validation tool:
[Pragmatic Validator Lite™](#)

Locating the Gateway Core ID

Log onto FDA Gateway




The screenshot shows the FDA Gateway WebTrader interface. At the top is a navigation bar with a home icon, 'WebTrader' text, a user icon, 'Help', and a 'Logout' link. Below this is a section titled 'My FDA submissions'. To the right of this section is a link for 'Other documents'. The main content is a table with columns: Submission name, Size, Center, Type, Status, and Date. One submission is listed: 'pyrethrum_board_of_kenya_er_10_10_09.tar.gz' with a size of 3.1 KB, center OCPP, and type SPL. The status column contains a bulleted list of links: 'Backup found', 'Receipt', and 'Acknowledgement' (marked as 'New'). The date is 'Oct 31, 2009 06:13:04 PM'.

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	pyrethrum_board_of_kenya_er_10_10_09.tar.gz	3.1 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM

- Log onto the FDA Gateway
- Select the “My FDA submissions” or “Other documents” hyperlinks

Selecting the File w/Core ID

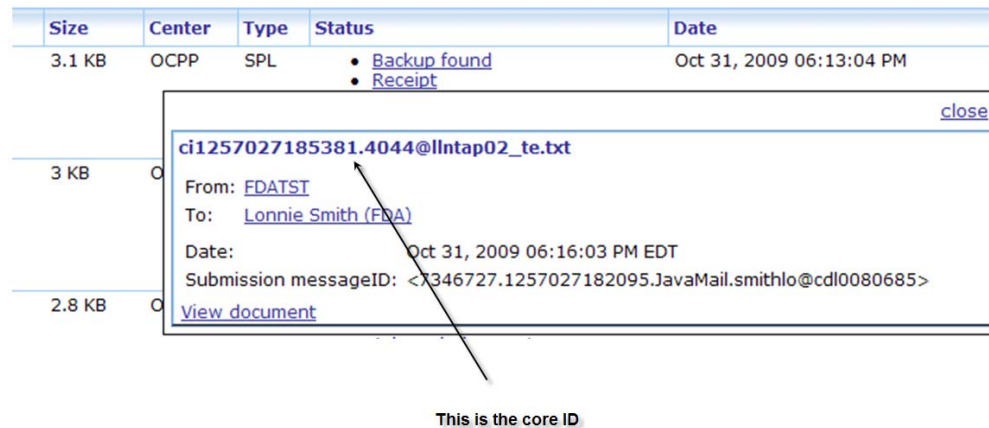
Center	Type	Status	Date
OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement <i>New</i>	Oct 31, 2009 06:13:04 PM



Click the "Acknowledgment" hyperlink

- The **first** "Acknowledgment" link should take you to window with core ID.


Finding the Core ID




- After selecting the “Acknowledgment” hyperlink, window should display.
- Core ID is located in top left of “Acknowledgment” window. (.txt is not part of the actual core ID)
- Use this core ID to reference submission when communicating with FDA about status or issue with SPL document.

Downloading Error Messages

Finding Error Messages




WebTrader



Help

Logout

My FDA submissions

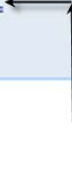
 [Other documents](#)

<input type="checkbox"/>	Submission name	Size	Center	Type	Status	Date
<input type="checkbox"/>	wellness_center.tar.gz	3 KB	OCP	SPL	<ul style="list-style-type: none">Backup foundReceiptAcknowledgementAcknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

- Logon to the FDA Gateway
- Select the “My FDA submissions” or “Other Documents” hyperlinks

Selecting Error Message

Size	Center	Type	Status	Date
3 KB	OCPP	SPL	<ul style="list-style-type: none">• Backup found• Receipt• Acknowledgement• Acknowledgement New	Oct 31, 2009 03:09:46 PM



Click on second (or third) "Acknowledgment" hyperlink

- Receipt of a second or third “Acknowledgment” hyperlink is indicative that there is an error with your submission.
- Click on second (and third, if available) “Acknowledgment” hyperlink.

Opening Error Messages

Size	Center	Type	Status	Date
3 KB	OCP	SPL	<ul style="list-style-type: none">Backup foundReceiptAcknowledgement <i>New</i>	Oct 31, 2009 03:09:46 PM

[close](#)

ci1257016187076.9279@lntap01_te.xml

2.8 KB O

From: [FDATST](#)

To: [Lonnie Smith \(FDA\)](#)

Date: Nov 1, 2009 12:34:11 PM EST

Submission messageID: <18012736.1257016184535.JavaMail.smithlo@cdl0080685>

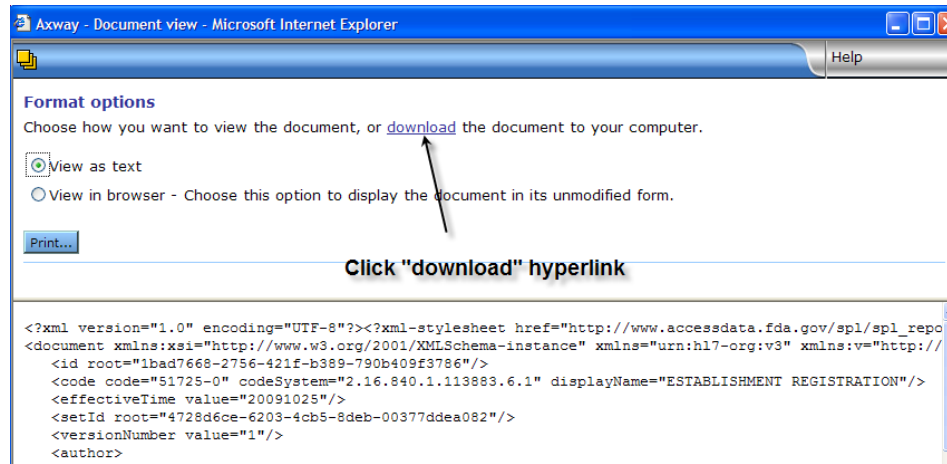
[View document](#)

2.7 KB O

Click "View document" hyperlink

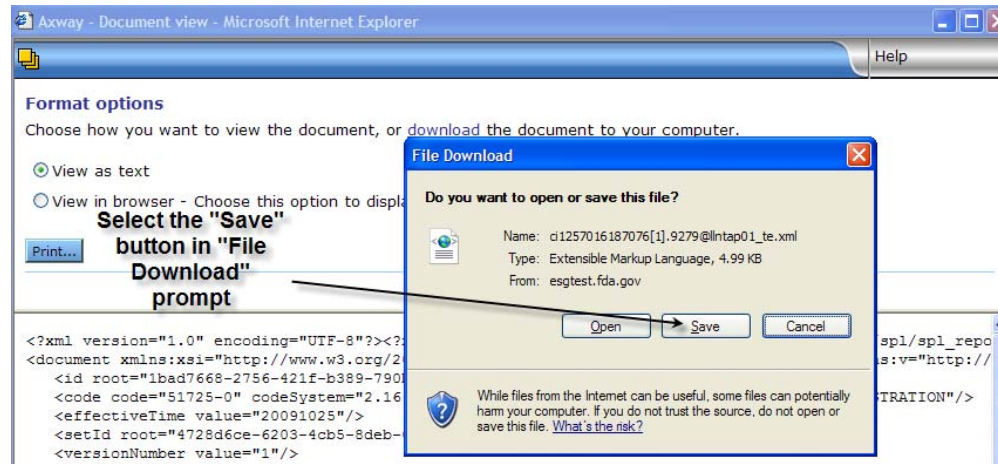
- Click the “View Document” located in the bottom left corner of Acknowledgment prompt window.

Downloading Error Message



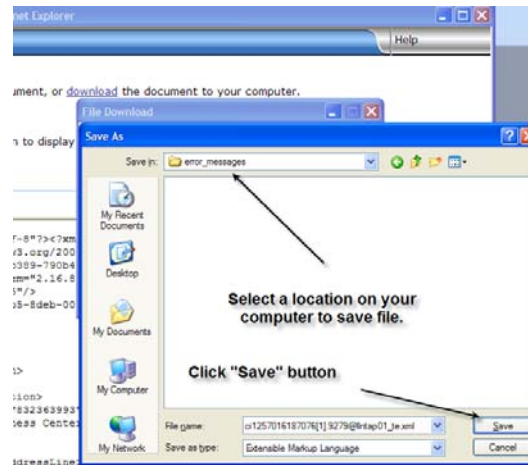
- Select the “download” hyperlink to download the error message to location on computer

Saving the Error Message Document



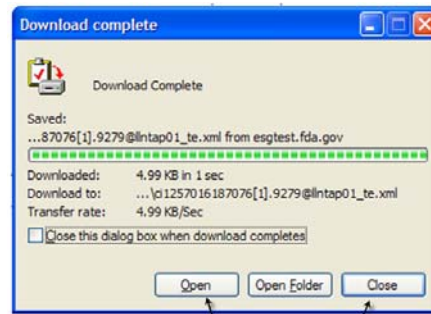
- Click the “Save” button in the “File Download” window prompt.

Saving the Error Message Document cont...



- Navigate to preferred location on your computer in which to store the error message.
- Click the “Save” button to save message in preferred location.

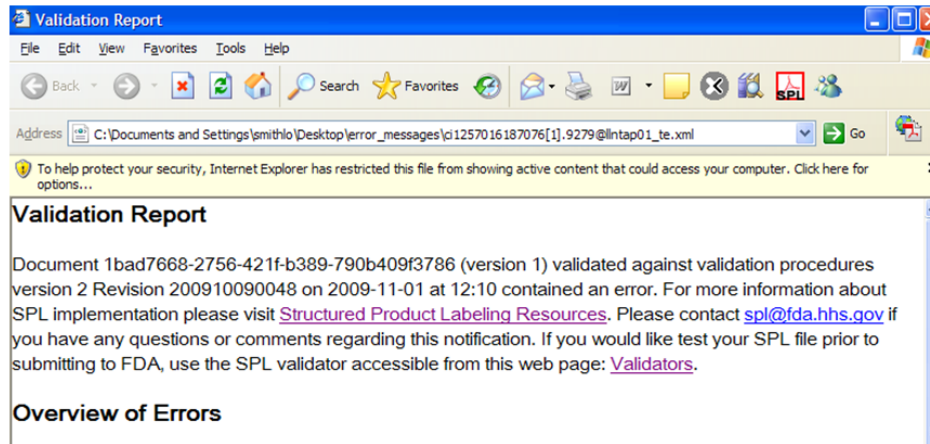
Completing Download



Select "Open" or "Close" buttons

- You can open the message from the “Download complete” window prompt
- You can also close the window and directly open from location on your computer where message was stored.

Review the Error Message



- Review the error message

Stay Informed

- Join FDA Data Standards Council listserv
- <http://www.fda.gov/ForIndustry/DataStandards/default.htm>



The screenshot shows the FDA Data Standards Council website. At the top is the U.S. Department of Health & Human Services header with the www.hhs.gov link. Below is the FDA U.S. Food and Drug Administration logo and a search bar. A navigation bar lists various FDA categories. The 'For Industry' section is highlighted, with a breadcrumb trail: Home > For Industry > Data Standards. On the left is a 'Data Standards' sidebar menu with links to Validators, Data Council, Structured Product Labeling, Individual Case Safety Reports, and Regulated Product Submission. The main content area is titled 'FDA Resources for Standards' and features a 'Sign up for email updates.' link with an arrow pointing to it. Below this is a paragraph about the council's mission and a link to 'Structured Product Labeling'.

U.S. Department of Health & Human Services www.hhs.gov

FDA U.S. Food and Drug Administration

A-Z Index Search go

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

For Industry Email this page Print this page Change Font Size

Home > For Industry > Data Standards

Data Standards

- Validators
- Data Council
- Structured Product Labeling
- Individual Case Safety Reports
- Regulated Product Submission

FDA Resources for Standards

 Sign up for email updates. ←

The FDA Data Standards Council coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards to ensure that common data standards are used throughout the agency.

[Structured Product Labeling](#)

SPL-related Technical Assistance/Questions

- Questions regarding **ANY** part of the SPL creation or submission process, please contact us.
- SPL e-mail account (spl@fda.hhs.gov)

QUESTIONS